EuPIA CHARTER

on raw material selection and exclusion

for printing inks and related products

1st Edition

(Replaces the EuPIA Exclusion Policy)

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European Printing Ink Association EuPIA - a sector of CEPE aisbl
Boulevard du Triomphe 172 • 1160 Brussels
+32 2 897 20 20 • eupia@cepe.org • www.eupia.org

INTRODUCTION & SCOPE

Since 1996 the printing ink industry in Europe has been committed to compliance with a voluntary initiative for the exclusion of certain raw materials (substances and mixtures) from printing inks and related products based on available hazard classification and/or toxicological evidence. This applies to existing and new raw materials. To maintain this recognised industry approach, the EuPIA Charter is looking after past, present and potential future human health hazards to protect the workers within the printing ink industry and at customer facilities as well as to ensure the safe use of printed articles. Physical and environmental hazard classifications are not subject to the Charter.
This industry initiative has been launched and is coordinated by EuPIA, nevertheless it is the individual companies – and not EuPIA as an industry association – that commit to the EuPIA Charter as defined in this document.
EuPIA member companies committing to the EuPIA Charter will be listed on the EuPIA website https://www.eupia.org/

PRINCIPLES

1. The EuPIA Charter applies to the manufacture and supply of all types of printing inks and related products, for use in any application and on any substrate in Europe[1].

2. Being a voluntary instrument, the EuPIA Charter is supplementary to relevant chemicals legislation, which take precedence.

3. Raw materials[2] subject to the Charter, are those substances or mixtures classified in one or more of the CLP hazard classes/categories listed below under the "Selection Criteria".

4. When a raw material becomes included in one of the categories in this Charter by reason of re-classification, by default EuPIA members are expected to substitute this material as soon as practicable, but within a year.

5. If it is found not to be possible to replace a raw material within one year in a specific application, the procedures established by this Charter will be applied. The chapter "Selection Criteria and Procedures" details the risk assessment possibilities for the continued use of certain raw materials under predefined and safe conditions.

6. The substances listed in Annexes 1 and 2 have already been subject to previous initiative and/ or have already been excluded under previous versions of the Charter (Exclusion Policy or List). Hence, they are considered as being phased out and are excluded for future intentional use.

7. A large number of raw materials used in printing inks are mixtures. Therefore, for specific technical and performance reasons it may be necessary, in an individual ink, to use a raw material that contains a substance listed in Annex 1 or 2 or classified according to I or II of the "Selection Criteria". In this case, the concentration of the substance in the raw material needs to be below the limits at which the raw material will be classified and labelled, accordingly.

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[1] EEA, EFTA and UK

[2] Raw materials used in printing inks and related products can be single substances, or mixtures of substances, according to the definition set in Article 2 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('CLP').

SELECTION CRITERIA & PROCEDURES

Substances and mixtures used as raw materials for the manufacture of printing inks and related products supplied to printers, classified in the below listed hazard classes/categories[3], shown with their respective hazard statement codes are subject to the Charter.

GROUP I Substances

• Genotoxic Carcinogen or Mutagen Cat. 1A & 1B [H350, H340]
• Acute Toxicity Cat. 1, 2 & 3 [H300, H301, H310, H311, H330, H331]
• STOT Single Exposure Cat. 1 [H370]

Substitution is mandatory: 1 year default substitution time applies. There is no possibility of extension even with detailed toxicological and risk assessment. Afterwards the raw material cannot be used anymore by any EuPIA members committed to the Charter.

In the exceptional case of an existing occupational exposure limit (OEL an extension for a further year is possible, provided that a risk assessment has been carried out and a substitution plan drawn up, which both have been approved by the EuPIA Technical Committee (ETC).

GROUP II Substances

• Non Genotoxic Carcinogen Cat 1 A & 1 B [H350]
• Toxic to Reproduction Cat. 1A & 1B [H360]
• STOT Repeated Exposure Cat. 1 [H372]
• Endocrine Disruptor for Human Health Cat. 1 [EUH380]

If substitution is possible for all EuPIA member companies having signed the Charter: **1 year default substitution time** applies. There is no need for a detailed toxicological and risk assessment. Afterwards the substance cannot be used anymore by any EuPIA members committed to the Charter.

When a member committed to the Charter inform the EuPIA secretariat that they are unable to substitute, a decision by the ETC will be taken. If the ETC accepts the arguments brought forward, following procedure applies:

i. The EuPIA Hazard Assessment Committee (HAC) will confirm the existing or derive a new DNEL[4] relevant for the substances in this group, for their exposure routes and uses.

[3] Applies both to harmonised classifications contained in CLP Annex VI Table 3 and to self-classifications assigned in accordance with Annex I to the CLP Regulation.

[4] The derived no-effect level (DNEL) is the level of exposure to a substance above which humans should not be exposed. The REACH regulation defines them as exposure levels beneath which a substance does not harm human health. In order to assess the hazard of a substance, the DNELs for the most probable ways of exposition (oral, dermal, inhalation) and the expected frequency and duration of exposure have to be toxicologically evaluated.

ii. Consequently, each affected EuPIA member company subject to this Charter will need to carry out an exposure assessment for all applicable use scenarios (ink production, converters, consumer) completed by a risk assessment and report to the EuPIA Secretariat on its execution. If safe-use cannot be demonstrated following exposure and risk assessment, phase-out activities need to be initiated immediately.

Every two years, companies benefiting from such an extended period of use must confirm to the EuPIA Secretariat the validity of the assessment or confirm that substitution has taken place in the meantime.

CONFIDENTIALITY CONDITIONS

EuPIA complies with EU competition rules and will therefore share commercial information only in aggregated and anonymised format to stakeholders. Stakeholders should refrain from engaging in any discussions on their company-specific data.

Access to confidential information contained in application or notification files is restricted to the EuPIA Secretariat and will not be shared with the Technical Committee and/or with EuPIA members (or non-members) in any way (for example in the minutes of meetings).

The name of the companies submitting a notification/application, as well as the details of these individual notifications/applications will not be shared with EuPIA members or non-members.

ANNEX 1

Substances Explicitly Excluded for Intentional Use (irrespective of hazard classification)

- Pigment colorants based on and compounds of antimony[5], arsenic, cadmium, chromium (VI), lead, mercury, selenium.

- Dye colourants:
  - Auramine (2465-27-2) (Basic Yellow 2 CI 41000)
  - Chrysoidine (532-82-1) (Basic Orange 2 CI 11270)
  - Fuchsin (632-99-5) (Basic Violet 14 CI 42510)
  - Induline (8004-98-6) (Solvent Blue 7 CI 50400)
  - Cresylene Brown (8005-78-5) (Basic Brown 4 CI 21010)

  Other soluble azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of Category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008.

- Solvents:
  - 2-Methoxyethanol (109-86-4)
  - 2-Ethoxyethanol (110-80-5)
  - 2-Methoxyethyl acetate (110-49-6)
  - 2-Ethoxyethyl acetate (111-15-9)
  - Monochlorobenzene (108-90-7)
  - Dichlorobenzene (25321-22-6)
  - Volatile chlorinated hydrocarbons, such as trichloroethylene (79-01-6), perchloroethylene (tetrachloroethylene, 127-18-4) and methylene chloride (75-09-2)
  - Volatile fluorochlorinated hydrocarbons
  - 2-Nitropropane (79-46-9)
  - Methanol (67-56-1)

- Plasticisers:
  - Chlorinated naphthalenes
  - Chlorinated paraffins
  - Monocresyl phosphate (26444-49-5)
  - Tricresyl phosphate (1330-78-5)
  - Monocresyl diphenyl phosphate (26444-49-5)

- Various compounds:
  - Diaminostilbene and derivatives
  - 2,4-Dimethyl-6-tertiary-butylphenol (1879-09-0)
  - 4,4'-Bis(dimethylamino)benzophenone (Michler's Ketone) (90-94-8)
  - Hexachlorocyclohexane

[5] With the exception of non-bio-available pigments in which antimony is a constituent of the crystal lattice and of organic derivatives not classified and labelled as per the exclusion criteria.

ANNEX 2

Substances which have already been subject to the Exclusion Policy :

CAS Number	Substance name	Hazard triggering exclusion
50-00-0	Formaldehyde	Carcinogen Category 1B
21245-02-3	2-ethylhexyl 4-(dimethylamino)benzoate (EHA)	Reprotoxic Category 1B
119313-12-1	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (BDMBP; Omnirad 369)	Reprotoxic Category 1B
2399-48-6	Tetrahydrofurfuryl acrylate (THFA)	Reprotoxic Category 1B
71868-10-5	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (Omnirad 907)	Reprotoxic Category 1B
2128-93-0	4-phenylbenzophenone (4-PBZ)	Reprotoxic Category 1B
10287-53-3	Ethyl-4-(dimethylamino)benzoate (EDB)	Reprotoxic Category 1B
616-45-5	2-pyrrolidone	Reprotoxic Category 1B
136-52-7	Cobalt bis(2-ethylhexanoate) (Co octoate)	Reprotoxic Category 1B
103170-26-9	Polyisocyanate, cycloaliphatic, blocked with 2-butanone oxime	Reprotoxic Category 1B
1530-32-1	Ethyl Triphenyl Phosphonium Bromide (ETPPB)	Acute Toxicity Category 3 (Oral) H301 Toxic if swallowed
24593-34-8	Cerium 2-ethylhexanoate	Reprotoxic Category 1B
149-57-5	2-ethyl hexanoic acid & all salts	Reprotoxic Category 1B
15956-58-8	Manganese 2-ethylhexanoate	Reprotoxic Category 1B
22464-99-9	Zirconium 2-ethylhexanoate	Reprotoxic Category 1B
19583-54-1	Iron-2-ethylhexanoate	Reprotoxic Category 1B
85203-81-2	Zinc ethylhexanoate	Reprotoxic Category 1B
301-10-0	Tin bis(ethylhexanoate)	Reprotoxic Category 1B
136-51-6	Calcium ethylhexanoate	Reprotoxic Category 1B
119-61-9	Benzophenone	Carcinogen Category 1B
111-76-2	2-butoxyethanol	Acute Toxicity Category 3 (inhalation) (H331)
163206-31-3	Hexan, 1,6-diisocyanato-, homopolymer, 3,5-dimethyl-1H-pyrazole blocked	STOT RE 1 H372 (inhalation)
75980-60-8	TPO Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide*	Reprotoxic Category 1B
119344-86-4	Omnirad 379*	Reprotoxic Category 1B

** Exemption still running for a maximum defined period of time, no usage at all possible after final 3rd year of exemption.*

- *TPO to be phased out by April 2027*
- *Omnirad 379 to be phased out by December 2027*

ANNEX 3

Continued use approved by EuPIA Technical Committee under this Charter

CAS/EC	Name	Hazard Category	Group
2235-00-9	N-vinyl caprolactam (NVC)	STOT RE 1 H372 (inhalation)	II
117527-94-3, 61901-87-9 & others including EC 938-781-3	Solvent Black	Reprotoxic Category 1B	II